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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,429	03/22/2002	John-Olov Jansson	003300-891	6573

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
HUNNICUTT, RACHEL KAPUST	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,429	JANSSON ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0102, 0402*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The use of the trademarks PDEXA™ (p. 23) and PQCT™ (p. 31) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "intensify" in claims 28 and 38 is a relative term which renders the claim indefinite. The term "intensify" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 17-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "obesity associated disorders" relates to a large number of possible disorders, however applicants only disclose the relationship of obesity and diabetes, hypertension, and heart disease (p. 1 of specification). One of skill in the art would not be able to envision the full scope of disorders encompassed by the claims.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 24 recites the limitation "said condition" in reference to claim 17. However, claim 17 does not refer to a "condition". There is insufficient antecedent basis for this limitation in the claim. Claims 25 and 26 recite the limitation "said medicinal product" in reference to claim 17, however claim 17 does not refer to a "medicinal product". There is insufficient antecedent basis for this limitation in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an IL-6 receptor agonist in order to decrease body weight, does not reasonably provide enablement for administering any substance that leads to an increased level of an IL-6 receptor agonist or for treating any obesity associated disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 17-38 are drawn to methods for treating obesity and/or obesity-associated disorders by administering a substance that leads to an increased level of IL-6 receptor agonist. IL-6 has been implicated in a number of biological functions, and often it is not clear if it has beneficial or harmful effects. For example, IL-6 levels are high in children with systemic juvenile chronic arthritis (Rooney *et al.* (1995), *Br. J. Rheumatol.* 34(5): 454-460). In addition, Applicant has not taught that an IL-6 receptor agonist would be useful in treating any obesity-associated disease other than by decreasing body weight. One of skill in the art would first need

to determine whether or not IL-6 was associated with an obesity-related disorder. Then one would need to determine whether IL-6 levels are increased or decreased in the disorder and whether it would beneficial to administer an IL-6 receptor agonist. Only then would one skilled in the art be able to practice the method as taught by Applicant.

Because of the lack of examples, the breadth of the claims, and the lack of direction provided by the Applicant, it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-26 and 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 05186367 (submitted by applicants January 10, 2002). Claims 17-26 and 31-37 are drawn to methods for treating obesity and/or obesity associated disorders by administering a substance that leads to an increased level of an IL-6 receptor agonist. JP 05186367 teaches a hypolipidemic drug comprising IL-6 which reduces the level of cholesterol in blood. As defined in the specification, elevated levels of cholesterol is an obesity associated disorder (p. 3). Cardiovascular diseases, which are generally recognized as being obesity associated disorders and are disclosed as such on p. 1 of the specification, are associated with high blood lipid levels such as cholesterol. Thus, claims 17-26 and 31-37 are anticipated by JP 05186367.

Claims 17-19, 25-26, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Metzger *et al.* (1997, *Am. J. Physiol.* 273: E262-E267). Claims 17-19, 25-26, and 36-37 are as stated above. Metzger *et al.* teach that mice injected with cells expressing the IL-6 gene exhibited decreased food consumption, reduced body weight, and reduced blood glucose levels. Thus, claims 17-19, 25-26, and 36-37 are anticipated by Metzger *et al.*

Claims 17-19, 25-26, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ettinger *et al.* (submitted by applicants January 10, 2002). Claims 17-19, 25-26, and 36-37 are as stated above. Ettinger *et al.* teach the administration of IL-6 to middle aged and old Rhesus monkeys (p. M137). Ettinger *et al.* also teach that body weight is reduced following IL-6 treatment. Thus, claims 17-19, 25-26, and 36-37 are anticipated by Ettinger *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05186367 or Metzger *et al.* or Ettinger *et al.* as applied to claims 17-26, and 31-37 above. Claim 27 is drawn to a method of treating obesity or an obesity-related disorder by administering an IL-6 receptor

agonist wherein the patient is at least 30 years old. JP 05186367, Metzger *et al.*, and Ettinger *et al.* all teach that IL-6 is useful for either reducing cholesterol levels in the blood or reducing body weight, however neither JP 05186367, Metzger *et al.*, nor Ettinger *et al.* teach administering IL-6 to patients at least 30 years old. Because IL-6 has already been shown to be successful in lowering cholesterol levels in the blood and lowering body weight, it would be obvious to administer IL-6 to a patient of any age in order to treat the patient for obesity or an obesity-related disease. The skilled artisan would be motivated to do so because JP 05186367, Metzger *et al.*, and Ettinger *et al.* have all shown that IL-6 is useful for either reducing cholesterol levels in the blood or reducing body weight. One of ordinary skill in the art would expect administering IL-6 to be successful in such treatments.

Claims 28-30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05186367 as applied to claims 17-19, 25-26, and 36-37 above, and further in view of Agnello *et al.* (submitted by applicants January 10, 2002). Claims 28-30 and 38 are drawn to methods of administering an IL-6 receptor agonist together with a factor that will intensify the effect of the IL-6 receptor agonist. JP 05186367 teaches administering IL-6, but it does not teach administering IL-6 in combination with anything else. Agnello *et al.* teach that leptin causes body weight loss. Agnello *et al.* also teach that IL-6 has been observed to cause body weight loss and/or food intake reduction (p. R916, first column). Because IL-6 and leptin have both been shown to cause body weight loss, it would be prima facie obvious to combine the two methods in order to form a combination that is to be used for the very same purpose. See *In re Kerkhoven* (205 USPQ 1069, CCPA 1980). One of ordinary skill in the art would have been motivated to combine the methods of JP 05186367 and Agnello *et al.* because they are both useful in decreasing body weight. One of ordinary skill in the art would have expected the combination to be successful because one would expect the effect to be intensified.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
9/17/04

SHARON L. TURNER, PH.D.
PATENT EXAMINER
9-17-04